notice to all parties, waive any rule or issue such orders that justice or the administration of FSMA requires.

PART 1990—IDENTIFICATION, CLASSIFICATION, AND REGULATION OF POTENTIAL OCCUPATIONAL CARCINOGENS

GENERAL

Sec.

THE OSHA CANCER POLICY

PRIORITY SETTING

REGULATION OF POTENTIAL OCCUPATIONAL CARCINOGENS

MODEL STANDARDS

AUTHORITY: Secs. 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 8–76 (41 FR 25059); and 29 CFR part 1911.

SOURCE: 45 FR 5282, Jan. 22, 1980, unless otherwise noted.

GENERAL

§ 1990.101 Scope.

This part establishes criteria and procedures for the identification, classification, and regulation of potential occupational carcinogens found in each workplace in the United States regulated by the Occupational Safety and Health Act of 1970 (the Act). The procedures contained in this part supplement the procedural regulations in other parts of this chapter. In the event of a conflict, the procedures contained in this part shall govern the identification, classification, and regulation of potential occupational carcinogens. This part may be referred to as ''The OSHA Cancer Policy.''

§ 1990.102 Purpose.

The Act provides, among other things, that

> the Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this section, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his or her working life. Development of standards under this section shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired (section 6(b)(5)).

It is the purpose of the regulations of this part to carry out the intent of the Act with respect to the identification, classification, and regulation of potential occupational carcinogens.

§ 1990.103 Definitions.

Terms used in this part shall have the meanings set forth in the Act. In addition, as used in this part, the following terms shall have the meanings set forth below:

Act means the Occupational Safety and Health Act of 1970 (Pub. L. 91–596, 84 Stat. 1590 *et seq.*, 29 U.S.C. 551 *et seq.).*

Administrator of EPA means the Administrator of the United States Environmental Protection Agency, or designee.

Chairperson of CPSC means the Chairman of the United States Consumer Product Safety Commission, or designee.

Commissioner of FDA means the Commissioner of the Food and Drug Administration, United States Department of Health and Human Services, or designee.

Director of NCI means the Director of the National Cancer Institute, United States Department of Health and Human Services, or designee.

Director of NIEHS means the Director of the National Institute of Environmental Health Sciences, United States Department of Health and Human Services, or designee.

Director of NIOSH means the Director of the National Institute for Occupational Safety and Health, United States Department of Health and Human Services, or designee.

Mutagenesis means the induction of heritable changes in the genetic material of either somatic or germinal cells.

Positive results in short-term tests means positive results in assays for two or more of the following types of effect:

(1) The induction of DNA damage and/or repair;

(2) Mutagenesis in bacteria, yeast, *Neurospora* or *Drosophila melanogaster;*

(3) Mutagenesis in mammalian somatic cells;

(4) Mutagenesis in mammalian germinal cells; or

(5) Neoplastic transformation of mammalian cells in culture.

Potential occupational carcinogen means any substance, or combination or mixture of substances, which causes an increased incidence of benign and/or malignant neoplasms, or a substantial decrease in the latency period between exposure and onset of neoplasms in humans or in one or more experimental mammalian species as the result of any oral, respiratory or dermal exposure, or any other exposure which results in the induction of tumors at a site other than the site of administration. This definition also includes any substance which is metabolized into one or more potential occupational carcinogens by mammals.

Secretary of HHS means the Secretary of the United States Department of Health and Human Services, or designee.

§ 1990.104 Scientific review panel.

(a) *General.* At any time, the Secretary may request the Director of NCI, the Director of NIEHS and/or the Director of NIOSH to convene a scientific review panel (''the panel'') to provide recommendations to the Secretary in the identification, classification, or regulation of any potential occupational carcinogen.

(b) *Membership.* The panel will consist of individuals chosen by the respective Director(s). The panel will consist of individuals who are appropriately qualified in the disciplines relevant to the issues to be considered, and who are employed by the United States. The panel does not constitute an advisory committee within the meaning of section 6(b) or 7(b) of the Act, or the Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770).

(c) *Report.* The Secretary shall request that the panel submit a report of its evaluation within ninety (90) days after the appointment of the members of the panel. The Secretary shall place a copy of the report in the record of any relevant rulemaking undertaken pursuant to this part and allow an appropriate time for public review and comment. If a panel is not established or fails to file a timely report, or if the Secretary determines that it is necessary to proceed without waiting for the panel's report, the Secretary may proceed in making any determination without such report.

(d) *Other aid and assistance.* Nothing herein precludes the Secretary from obtaining advice or other aid from any person or organization including NCI, NIEHS, and NIOSH.

§ 1990.105 Advisory committees.

The Secretary may appoint an Advisory Committee, pursuant to sections 6(b) and 7 of the Act, and 29 CFR part

1912, concerning any potential occupational carcinogen. The Secretary shall require the Advisory Committee to submit its recommendations to assist the Secretary in standard setting no later than ninety (90) days from the date of the Advisory Committee's appointment, unless extended by the Secretary for exceptional circumstances. If an Advisory Committee fails to file a timely report, the Secretary may proceed in standard setting activities without such a report.

§ 1990.106 Amendments to this policy.

(a) *Initiation of review of this policy*—(1) *Secretary's request.* No later than every three (3) years from the effective date of this part, or from the last general review, the Secretary shall request the Director of NCI, the Director of NIEHS and/or the Director of NIOSH, to review this part and render their opinions on whether significant scientific or technical advances made since the effective date of this part warrant any amendment to this part. The request shall ask that the answer be provided to the Secretary within one hundred twenty (120) days.

(2) *Recommendations by the institutes.* At any time, the Director of NCI, the Director of NIEHS and/or the Director of NIOSH may submit recommendations to the Secretary for amendments to this part whenever any of them believes that scientific or technical advances justify such amendments.

(3) *Petitions from the public.* (i) Any interested person may petition the Secretary concerning amendments to this part based upon substantial new issues or substantial new evidence.

(ii) For the purposes of this part, substantial new evidence is evidence which differs significantly from that presented in establishing this part, including amendments.

(iii) For the purposes of this part, substantial new issues are issues which differ significantly from those upon which the Secretary has reached a conclusion in the rulemaking establishing this part (including the conclusions reached in the preamble).

(iv) Each petition to amend this part shall contain at least the following information:

(A) Name and address of petitioner;

(B) The provisions which the petitioner believes are inappropriate;

(C) All data, views and arguments relied upon by the petitioner; and

(D) A detailed statement and analysis as to why the petitioner believes that the data, views and arguments presented by petitioner:

(*1*) Constitute substantial new issues or substantial new evidence; and

(*2*) Are so significant as to warrant amendment of this part.

(b) *Response to recommendations and petitions*—(1) *By the institutes.* Whenever any Director recommends an amendment to this part, the Secretary shall, within one hundred twenty (120) days after receipt of the recommendation, publish in the FEDERAL REGISTER, a notice which:

(i) States the reasons why the Secretary has determined not to commence a rulemaking proceeding to amend this part, in whole or in part, at that time; or

(ii) Commences a rulemaking proceeding to consider amending this part accordingly; or

(iii) Appoints an Advisory Committee as provided for by §1990.105 of this part and sections 6(b) and 7 of the Act.

(2) *By the public.* Within ninety (90) days, or as soon thereafter as possible, after receipt of a petition pursuant to §1990.106(a)(3), the Secretary shall:

(i) Refer the petition to the Director of NCI, the Director of NIEHS and/or the Director of NIOSH, in which case the provisions of §1990.106 (a)(1) and (b)(1) are applicable; or

(ii) Appoint an advisory committee;

(iii) Deny the petition, briefly giving the reasons therefor; or

(iv) Commence a rulemaking proceeding to consider amending this part accordingly.

(3) *On the Secretary's motion.* At any time, the Secretary may, on his own motion, commence a rulemaking proceeding to amend this part.

[45 FR 5282, Jan. 22, 1980; 45 FR 43405, June 27, 1980]

THE OSHA CANCER POLICY

§ 1990.111 General statement of regulatory policy.

(a) This part establishes the criteria and procedures under which substances

will be regulated by OSHA as potential occupational carcinogens. Although the conclusive identification of ''carcinogens'' is a complex matter ''on the frontiers of science,'' (*IUD* v. *Hodgson* 499 F. 2d 467, 474 (D.C. Cir. 1974)), responsible health regulatory policy requires that criteria should be specified for the identification of substances which should be regulated as posing potential cancer risks to workers.

(b) The criteria established by this part are based on an extensive review of scientific data and opinions. The part provides for amending these criteria in light of new scientific developments. Decisions as to whether any particular substance meets the criteria or not will be consistent with the policies and procedures established by this part and will be based upon scientific evaluation of the evidence on that substance.

(c) This part applies to individual substances, groups of substances, or combinations or mixtures of substances which may be found in workplaces in the United States. In individual rulemaking proceedings under this part, the identity and range of substances and mixtures to be covered by the standard will be specified and the appropriateness of applying the available evidence to the range of substances and mixtures proposed for regulation will be subject to scientific and policy review.

(d) Potential occupational carcinogens will be identified and classified on the basis of human epidemiological studies and/or experimental carcinogenesis bioassays in mammals. Positive results in short term tests will also be used as concordant evidence.

(e) Potential occupational carcinogens will be classified and regulated in accordance with the policy. The scientific evidence as to whether individual substances meet these criteria will be considered in individual rulemakings. The issues which may be considered in these rulemakings will be limited as specified herein.

(f) This policy provides for the classification of potential occupational carcinogens into two categories depending on the nature and extent of the available scientific evidence. The two categories of potential occupational carcinogens may be regulated differently.

(g) The policy establishes a procedure for setting priorities and making them public.

(h) Worker exposure to Category I Potential Carcinogens will be reduced primarily through the use of engineering and work practice controls.

(i) Worker exposure to Category II Potential Carcinogens will be reduced as appropriate and consistent with the statutory requirements on a case-by-case basis in the rulemaking proceedings on individual substances. Any permissible exposure level so established shall be met primarily through engineering and work practice controls.

(j) The assessment of cancer risk to workers resulting from exposure to a potential occupational carcinogen will be made on the basis of available data. Because of the uncertainties and serious consequences to workers if the estimated risk is understated, cautious and prudent assumptions will be utilized to perform risk assessments.

(k) Where the Secretary determines that one or more suitable substitutes exist for certain uses of Category I Potential Carcinogens that are less hazardous to humans, a no occupational exposure level shall be set for those uses, to be achieved solely through the use of engineering and work practice controls to encourage substitution. In determining whether a substitute is suitable, the Secretary will consider the technological and economic feasibility of the introduction of the substitute, including its relative effectiveness and other relevant factors, such as regulatory requirements and the time needed for an orderly transition to the substitute.

[45 FR 5282, Jan. 22, 1980, as amended at 46 FR 5881, Jan. 21, 1981]

§ 1990.112 Classification of potential carcinogens.

The following criteria for identification, classification and regulation of potential occupational carcinogens will be applied, unless the Secretary considers evidence under the provisions of §§ 1990.143, 1990.144 and 1990.145 and determines that such evidence warrants an exception to these criteria.

(a) *Category I Potential Carcinogens.* A substance shall be identified, classified, and regulated as a Category I Potential Carcinogen if, upon scientific evaluation, the Secretary determines that the substance meets the definition of a potential occupational carcinogen in (1) humans, or (2) in a single mammalian species in a long-term bioassay where the results are in concordance with some other scientifically evaluated evidence of a potential carcinogenic hazard, or (3) in a single mammalian species in an adequately conducted long-term bioassay, in appropriate circumstances where the Secretary determines the requirement for concordance is not necessary. Evidence of concordance is any of the following: positive results from independent testing in the same or other species, positive results in short-term tests, or induction of tumors at injection or implantation sites.

(b) *Category II Potential Carcinogens.* A substance shall be identified, classified, and regulated as a Category II Potential Carcinogen if, upon scientific evaluation, the Secretary determines that:

(1) The substance meets the criteria set forth in §1990.112(a), but the evidence is found by the Secretary to be only ''suggestive''; or

(2) The substance meets the criteria set forth in §1990.112(a) in a single mammalian species without evidence of concordance.

PRIORITY SETTING

§ 1990.121 Candidate list of potential occupational carcinogens.

(a) *Contents.* The Secretary shall prepare a list of substances (the ''Candidate List'') which are reported to be present in any American workplace and which, on the basis of a brief scientific review of available data, may be considered candidates for further scientific review and possible regulation as Category I Potential Carcinogens or Category II Potential Carcinogens. For the purposes of this paragraph, ''available data'' means:

(1) The data submitted by any person;

(2) Any data referred to by the Secretary of HHS or by the Director of NIOSH, either in the latest list entitled ''Suspected Carcinogens'' or any other communication;

(3) Literature referred to in U.S. Public Health Service, Publication No. 149;

(4) Data summarized and reviewed in Monographs of the International Agency for Research on Cancer (IARC) of the World Health Organization;

(5) The Toxic Substances Control Act Inventory of Chemical Substances, published by the Administrator of EPA;

(6) The Secretary of HHS's Annual Report to the President and the Congress as required by the Community Mental Health Centers Extension Act of 1978, section 404(a)(9), 42 U.S.C. 285.

(7) Any other relevant data of which the Secretary has actual knowledge.

(b) *Tentative classification.* The Secretary may tentatively designate substances on the Candidate List as candidates for classification as Category I Potential Carcinogens or as Category II Potential Carcinogens, or may list substances without a tentative designation, based on the brief scientific review of available data for the purpose of initiating a more extensive scientific review.

(c) *No legal rights established.* The inclusion or exclusion of any substance from the Candidate List shall not be subject to judicial review nor be the basis of any legal action, nor shall the exclusion of any substance from the list prevent the regulation of that substance as a potential occupational carcinogen. The inclusion of a substance on the Candidate List and its possible tentative designation as a Category I Potential Carcinogen or a Category II Potential Carcinogen therein do not reflect a final scientific determination that the substance is, in fact, a Category I Potential Carcinogen or a Category II Potential Carcinogen. It is a policy determination based on the brief scientific review that the Secretary should conduct a thorough review of all relevant scientific data concerning the substance.

EFFECTIVE DATE NOTE: At 48 FR 243, Jan. 4, 1983, in §1990.121, paragraphs (a) and (b) were stayed in order to evaluate the impact of publishing the Candidate Lists and Priority

List and to reconsider the criteria used in establishing the lists (see also 47 FR 187, Jan. 5, 1982).

§ 1990.122 Response to petitions.

Whenever the Secretary receives any information submitted in writing by any interested person concerning the inclusion or omission of any substance from the Candidate List, the Secretary shall briefly review the information and any other available data, as defined in § 1990.121(a). The results of the Secretary's review shall be transmitted to the petitioner, together with a short statement of the Secretary's reasons therefor, and made public upon request.

EFFECTIVE DATE NOTE: At 48 FR 243, Jan. 4, 1983, § 1990.122 was stayed in order to evaluate the impact of publishing the Candidate List and Priority Lists and to reconsider the criteria used in establishing the lists (see also 47 FR 187, Jan. 5, 1982).

§ 1990.131 Priority lists for regulating potential occupational carcinogens.

The Secretary shall establish two priority lists for regulating potential occupational carcinogens. One list should include approximately ten (10) candidates for rulemaking as Category I Potential Carcinogens; the other approximately ten (10) candidates for rulemaking as Category II Potential Carcinogens. The order of placement of substances on these lists will not reflect the Secretary's determination of the exact order in which these substances should be regulated in rulemaking proceedings but rather a policy determination that the Secretary plans to address some or all of these substances prior to proceeding with a thorough scientific review of data concerning other substances on the Candidate List. The inclusion or exclusion of any substance on these lists shall not be subject to judicial review or be the basis for any legal action. The Secretary may regulate a potential occupational carcinogen which has not been placed on these lists. The inclusion of a substance on either of these lists does not reflect a final scientific determination that the substance is, in fact, a Category I Potential Carcinogen or a Category II Potential Carcinogen.

EFFECTIVE DATE NOTE: At 48 FR 243, Jan. 4, 1983, § 1990.131 was stayed in order to evaluate the impact of publishing the Candidate List and Priority Lists and to reconsider the criteria used in establishing the lists (see also 47 FR 187, Jan. 5, 1982).

§ 1990.132 Factors to be considered.

(a) The setting of priorities is a complex matter which requires subjective and policy judgments. It is not appropriate to establish a rigid formula or to assign predetermined weight to each factor. The identification of some of the elements is to guide the OSHA staff and inform the public on the development of priorities. It is not intended to create any legal rights with respect to the setting of priorities.

(b) Some factors which may be taken into account in setting priorities for regulating potential occupational carcinogens, when such data are available, are:

(1) The estimated number of workers exposed;

(2) The estimated levels of human exposure;

(3) The levels of exposure to the substance which have been reported to cause an increased incidence of neoplasms in exposed humans, animals or both;

(4) The extent to which regulatory action could reduce not only risks of contracting cancer but also other occupational and environmental health hazards;

(5) Whether the molecular structure of the substance is similar to the molecular structure of another substance which meets the definition of a potential occupational carcinogen;

(6) Whether there are substitutes that pose a lower risk of cancer or other serious human health problems, or available evidence otherwise suggests that the social and economic costs of regulation would be small; and

(7) OSHA will also consider its responsibilities for dealing with other health and safety hazards and will consider the actions being taken or planned by other governmental agencies in dealing with the same or similar health and safety hazards.

§ 1990.133 Publication.

(a) The Secretary shall publish the Candidate List in the FEDERAL REGISTER at least annually.

(b) The Secretary shall publish the Priority Lists in the FEDERAL REGISTER at least every six months and may seek public comment thereon.

(c) The Secretary may periodically publish in the FEDERAL REGISTER a notice requesting information concerning the classification and establishment of priorities for substances on the Candidate List together with a brief statement describing the type of information being sought.

EFFECTIVE DATE NOTE: At 48 FR 243, Jan. 4, 1983, § 1990.133 was stayed in order to evaluate the impact of publishing the Candidate List and Priority Lists and to reconsider the criteria used in establishing the lists (see also 47 FR 187, Jan. 5, 1982).

REGULATION OF POTENTIAL OCCUPATIONAL CARCINOGENS

§ 1990.141 Advance notice of proposed rulemaking.

(a) Within thirty (30) days after OSHA initiates a study concerning the economic and/or technological feasibility of specific standards that might be applied in the regulation of a potential occupational carcinogen, the Secretary will normally publish, in the FEDERAL REGISTER, a notice which includes at least the following:

(1) The name of the substance(s),

(2) The scope of the study, including where possible,

(i) Affected industries,

(ii) Levels of exposure being studied,

(iii) The anticipated completion date of the study;

(3) A brief summary of the available data on health effects;

(4) An estimate of when the Secretary anticipates the issuance of a proposal;

(5) An invitation to interested parties to provide relevant information;

(6) A statement that persons wishing to provide OSHA with their own study should complete it within 30 days after the anticipated proposal date; and

(7) A statement of the procedural requirements that must be met before substantial new issues or substantial new evidence will be considered in the proceeding pursuant to § 1990.145.

(b) Where the Secretary determines to discontinue a feasibility study, the Secretary should publish, within 30 days, a notice in the FEDERAL REGISTER so indicating.

§ 1990.142 Initiation of a rulemaking.

Where the Secretary decides to regulate a potential occupational carcinogen, the Secretary shall initiate a rulemaking proceeding in accordance with one of the following procedures, as appropriate.

(a) *Notice of proposed rulemakings (section 6(b) of the Act)*—(1) *General.* The Secretary may issue a notice of proposed rulemaking in the FEDERAL REGISTER, pursuant to section 6(b) of the Act and part 1911 of this chapter. The notice shall provide for no more than a sixty (60) day comment period, and may provide for a hearing, which shall be scheduled for no later than one hundred (100) days after publication of the Notice of Proposed Rulemaking. The commencement of the hearing may be postponed once, for no more than thirty (30) days, for good cause shown.

(2) *Provisions of the proposed standard for Category I Potential Carcinogens.* Whenever the Secretary issues a notice of proposed rulemaking to regulate a substance as a Category I Potential Carcinogen:

(i) The proposed standard shall contain at least provisions for scope and application, definitions, notification of use, a permissible exposure limit, monitoring, regulated areas, methods of compliance including the development of a compliance plan, respiratory protection, protective clothing and equipment, housekeeping, waste disposal, hygiene facilities, medical surveillance, employee information and training, signs and labels, recordkeeping, and employee observation of monitoring as set forth in § 1990.151, unless the Secretary explains why any or all such provisions are not appropriate;

(ii) The model standard set forth in § 1990.151 shall be used as a guideline, and

(iii) The permissible exposure limit shall be achieved primarily through engineering and work practice controls except that if a suitable substitute is

available for one or more uses no occupational exposure shall be permitted for those uses.

(3) *Provisions of the proposed standard for Category II Potential Carcinogens.* Whenever the Secretary issues a Notice of Proposed Rulemaking to regulate a substance as a Category II Potential Carcinogen:

(i) The proposed standard shall contain at least provisions for scope and application, definitions, notification of use, monitoring, respiratory protection, protective clothing and equipment, housekeeping, waste disposal, medical surveillance, employee information and training, recordkeeping and employee observation of monitoring as set forth in §1990.151, unless the Secretary explains why any or all such provisions are not appropriate; and

(ii) The model standard set forth in §1990.151 shall be used as a guideline; and

(iii) Worker exposure to Category II Potential Carcinogens will be reduced as appropriate and consistent with the statutory requirements on a case-by-case basis in the individual rulemaking proceedings. Any permissible exposure level so established shall be met primarily through engineering and work practice controls.

(b) *Emergency temporary standards (section 6(c) of the Act)*—(1) *General.* The Secretary may issue an Emergency Temporary Standard (ETS) for a Category I Potential Carcinogen in accordance with section 6(c) of the Act.

(2) *Provisions of the ETS.* (i) The ETS shall contain at least provisions for scope and application, definitions, notification of use, a permissible exposure limit, monitoring, methods of compliance including the development of a compliance plan, respiratory protection, protective clothing and equipment, housekeeping, waste disposal, medical surveillance, employee information and training, signs and labels, recordkeeping and employee observation of monitoring, unless the Secretary explains why any or all such provisions are not appropriate.

(ii) The model standard set forth in §1990.152 shall be used as a guideline.

(iii) The permissible exposure limit shall be achieved through any practicable combination of engineering controls, work practice controls and respiratory protection.

[45 FR 5282, Jan. 22, 1980, as amended at 46 FR 5881, Jan. 21, 1981]

§1990.143 General provisions for the use of human and animal data.

Human and animal data which are scientifically evaluated to be positive evidence for carcinogenicity including the following policies shall be uniformly relied upon for the identification of potential occupational carcinogens. Arguments challenging the following provisions or their application to specific substances will be considered in individual rulemaking proceedings only if the evidence presented in support of the arguments meets the criteria for consideration specified in §1990.144 or §1990.145.

(a) *Positive human studies.* Positive results obtained in one or more human epidemiologic studies will be used to establish the qualitative inference of carcinogenic hazards to workers.

(b) *Positive animal studies.* Positive results obtained in one or more experimental studies conducted in one or more mammalian species will be used to establish the qualitative inference of carcinogenic hazard to workers. Arguments that positive results obtained in mammalian species should not be relied upon will be considered only if evidence is presented which meets the criteria for consideration specified in §1990.144(c) or 1990.144(f).

(c) *Non-positive human studies.* Positive results in human or mammalian studies generally will be used for the qualitative identification of potential occupational carcinogens, even where non-positive results from human studies exist. Such non-positive results will be considered by the Secretary only if the studies or results meet the criteria set forth in §1990.144(a).

(d) *Non-positive animal studies.* Positive results in one or more mammalian studies will be used for the qualitative identification of potential occupational carcinogens, even where non-positive studies exist in other mammalian species. Where non-positive and positive results exist in studies in the same species, the non-positive results will be evaluated.

(e) *Spontaneous tumors.* Positive results in human or mammalian studies for the induction or acceleration of induction of tumors of a type which occurs ''spontaneously'' in unexposed individuals will be used for the qualitative identification of potential occupational carcinogens.

(f) *Routes of exposure.* (1) Positive results in studies in which mammals are exposed via the oral, respiratory or dermal routes will be used for the qualitative identification of potential occupational carcinogens, whether tumors are induced at the site of application or distant sites.

(2) Positive results in studies in which mammals are exposed via any route of exposure and in which tumors are induced at sites distant from the site of administration will be used for the qualitative identification of potential occupational carcinogens.

(3)(i) Positive results in mammalian studies in which tumors are induced only at the site of administration, in which a substance or mixture of substances is administered by routes other than oral, respiratory or dermal, will be used as ''concordant'' evidence that a substance is a potential occupational carcinogen.

(ii) Arguments that such studies should not be relied upon will be considered only if evidence which meets the criteria set forth in §1990.144(b) is provided.

(g) *Use of high doses in animal testing.* Positive results for carcinogenicity obtained in mammals exposed to high doses of a substance will be used to establish the qualitative inference of carcinogenic hazard to workers. Arguments that such studies should not be relied upon will be considered only if evidence which meets the criteria set forth in §1990.144(d) is provided.

(h) *''Threshold'' or ''No-effect'' Levels.* No determination will be made that a ''threshold'' or ''no-effect'' level of exposure can be established for a human population exposed to carcinogens in general, or to any specific substance.

(i) *Benign tumors.* Results based on the induction of benign or malignant tumors, or both, will be used to establish a qualitative inference of carcinogenic hazard to workers. Arguments that substances that induce benign tumors do not present a carcinogenic risk to workers will be considered only if evidence that meets the criteria set forth in §1990.144(e) is provided.

(j) *Statistical evaluation.* Statistical evaluation will be used in the determination of whether results in human, animal or short-term studies provide positive evidence for carcinogenicity, but will not be the exclusive means for such evaluation.

(k) *Carcinogenicity of metabolites.* A substance which is metabolized by mammals to yield one or more potential occupational carcinogens will itself be identified and classified as a potential occupational carcinogen, whether or not there is direct evidence that it induces tumors in humans or experimental animals. Evidence for such metabolism will normally be derived from *in vivo* studies in mammals. In appropriate circumstances, evidence may be derived from *in vitro* studies of mammalian tissues or fractions thereof. Arguments that evidence from *in vivo* metabolic studies in mammals is not relevant to the inference of carcinogenic hazard to humans will be considered only if such evidence meets the criteria set forth in §1990.144(c).

[45 FR 5282, Jan. 22, 1980; 45 FR 43405, June 27, 1980]

§1990.144 Criteria for consideration of arguments on certain issues.

Arguments on the following issues will be considered by the Secretary in identifying or classifying any substance pursuant to this part, if evidence for the specific substance subject to the rulemaking conforms to the following criteria. Such arguments and evidence will be evaluated based upon scientific and policy judgments.

(a) *Non-positive results obtained in human epidemiologic studies.* Non-positive results obtained in human epidemiologic studies regarding the substance subject to the rulemaking or to a similar or closely related substance will be considered by the Secretary only if they meet the following criteria:

Criteria. (i) The epidemiologic study involved at least 20 years' exposure of a group of subjects to the substance and at least 30 years' observation of the subjects after initial exposure;

(ii) Documented reasons are provided for predicting the site(s) at which the substance would induce cancer if it were carcinogenic in humans; and

(iii) The group of exposed subjects was large enough for an increase in cancer incidence of 50% above that in unexposed controls to have been detected at any of the predicted sites.

Arguments that non-positive results obtained in human epidemiologic studies should be used to establish numerical upper limits on potential risks to humans exposed to specific levels of a substance will be considered only if criteria (i) and (ii) are met and, in addition:

(iv) Specific data on the level of exposure of the group of workers are provided, based either on direct measurements made periodically throughout the period of exposure, or upon other data which provide reliable evidence of the magnitude of exposure.

(b) *Tumors induced at site of administration.* Arguments that tumors at the site of administration should not be considered will be considered only if:

(i) The route of administration is not oral, respiratory or dermal; and

(ii) Evidence is provided which establishes that induction of local tumors is related to the physical configuration or formulation of the material administered (e.g., crystalline form or dimensions of a solid material, or matrix of an impregnated implant) and that tumors are not induced when the same material is administered in a different configuration or formula.

(c) *Metabolic differences.* Arguments that differences in metabolic profiles can be used to demonstrate that a chemical found positive in an experimental study in a mammalian species would pose no potential carcinogenic risk to exposed workers will be considered by the Secretary only if the evidence presented for the specific substance subject to the rulemaking meets the following criteria:

Criteria. (i) A complete metabolic profile, including identities of trace metabolites, is presented for the experimental animal species;

(ii) A complete metabolic profile, including identities of trace metabolites, is available for a human population group representative of those who are occupationally exposed;

(iii) Documented evidence is provided for ascribing the carcinogenic activity of the substance in the test animal species to metabolite(s) produced only in that species and not in humans; and

(iv) Documented evidence is provided to show that other metabolites produced also in humans have been adequately tested and have not been shown to be carcinogenic.

(d) *Use of high doses in animal testing.* Arguments that positive results obtained in carcinogenesis bioassays with experimental animals subjected to high doses of a substance are not relevant to potential carcinogenic risks to exposed workers will be considered by the Secretary only if the evidence for the specific substance subject to the rulemaking meets the following criteria:

Criteria. (i) Documented evidence is presented to show that the substance in question is metabolized by the experimental animal species exposed at the dose levels used in the bioassay(s) to metabolic products which include one or more that are not produced in the same species at lower doses.

(ii) Documented evidence is presented to show that the metabolite(s) produced only at high doses in the experimental animal species are the ultimate carcinogen(s) and that the metabolites produced at low doses are not also carcinogenic; and

(iii) Documented evidence is presented to show that the metabolite(s) produced only at high doses in the experimental animal species are not produced in humans exposed to low doses.

(e) *Benign tumors.* The Secretary will consider evidence that the substance subject to the rulemaking proceeding is capable only of inducing benign tumors in humans or experimental animals provided that the evidence for the specific substance meets the following criteria:

Criteria. (i) Data are available from at least two well-conducted bioassays in each of two species of mammals (or from equivalent evidence in more than two species);

(ii) Each of the bioassays to be considered has been conducted for the full lifetime of the experimental animals;

(iii) The relevant tissue slides are made available to OSHA or its designee and the diagnoses of the tumors as benign are made by at least one qualified pathologist who has personally examined each of the slides and who provides specific diagnostic criteria and descriptions; and

(iv) All of the induced tumors must be shown to belong to a type which is known not to progress to malignancy or to be at a benign stage when observed. In the latter case, data must be presented to show that multiple sections of the affected organ(s)

were adequately examined to search for invasion of the tumor cells into adjacent tissue, and that multiple sections of other organs were adequately examined to search for tumor metastases.

(f) *Indirect mechanisms.* The Secretary will consider evidence that positive results obtained in a carcinogenesis bioassay with experimental animals are not relevant to a determination of a carcinogenic risk to exposed workers, if the evidence demonstrates that the mechanism by which the observed tumor incidence is effected is indirect and would not occur if humans were exposed. As examples, evidence will be considered that a substance causes a carcinogenic effect by augmenting caloric intake or that the carcinogenic effect from exposure to a substance is demonstrated to be the result of the presence of a carcinogenic virus and it is demonstrated that, in either case, the effect would not take place in the absence of the particular carcinogenic virus or the augmented caloric intake.

[45 FR 5282, Jan. 22, 1980, as amended at 46 FR 5881, Jan. 21, 1981]

§ 1990.145 Consideration of substantial new issues or substantial new evidence.

(a) *Substantial new issues.* Notwithstanding any other provision of this part, the Secretary will consider in a rulemaking proceeding on a specific substance any substantial new issues upon which the Secretary did not reach a conclusion in the rulemaking proceeding(s) underlying this part including conclusions presented in the preamble.

(b) *Substantial new evidence.* Notwithstanding any other provision of this part, the Secretary will consider in a rulemaking proceeding on a specific substance any arguments, data or views which he determines are based upon substantial new evidence which may warrant the amendment of one or more provisions of this part. For the purposes of this part, ''substantial new evidence'' is evidence directly relevant to any provision of this part and is based upon data, views or arguments which differ significantly from those presented in establishing this part, including amendments thereto.

(c) *Petitions for consideration of substantial new evidence*—(1) *Petition.* Any interested person may file a written petition with the Secretary to consider ''substantial new evidence'' or one or more ''substantial new issues'' which contains the information specified in paragraph (c)(2) of this section. The Secretary shall treat such a petition as a request to amend this part, as well as a petition to consider ''substantial new evidence''.

(2) *Contents.* Each petition for consideration of ''substantial new evidence'' or one or more ''substantial new issues'' shall contain at least the following information:

(i) Name and address of the petitioner;

(ii) All of the data, views and arguments that the petitioner would like the Secretary to consider;

(iii) The provision or provisions that petitioner believes are inappropriate or should be added to this part in light of the new data, views, and arguments;

(iv) A statement which demonstrates that the data, views, and arguments relied upon by petitioners are directly relevant to the substance or class of substances that is the subject of a rulemaking or an Advance Notice of Proposed Rulemaking;

(v) A detailed statement and analysis as to why the petitioner believes that the data, views, and arguments presented by the petitioner:

(A) Differ significantly from those presented in the proceeding(s) which establish this part;

(B) Are so substantial as to warrant amendment of this part; and

(C) Constitute a new issue or new evidence within the meaning of paragraphs (a) and (b) of this section.

(3) *Deadline for petitions.* (i) Petitions which comply with paragraph (c) of this section, shall be filed in accordance with the schedule set forth in the Advanced Notice of Proposed Rulemaking.

(ii) In extraordinary cases the Secretary may consider evidence submitted after the deadline if the petitioner establishes that the evidence relied upon was not available and could not have reasonably been available in

whole or substantial part by the deadline and that it is being submitted at the earliest possible time.

(d) *Secretary's response.* (1) The Secretary shall respond to petitions under this paragraph in accordance with §1990.106.

(2) Whenever the Secretary determines that the ''substantial new issue'' or the ''substantial new evidence'' submitted under this paragraph is sufficient to initiate a proceeding to amend this part, the Secretary shall:

(i) Issue a notice to consider amendment to this part and not proceed on the rulemaking concerning the individual substance until completion of the amendment proceeding; or

(ii) Issue a notice to consider amendment to this part and consolidate it with the proceeding on the individual substance.

§1990.146 Issues to be considered in the rulemaking.

Except as provided in §1990.145, after issuance of the advance notice of rulemaking, the proceedings for individual substances under this part shall be limited to consideration of the following issues:

(a) Whether the substance, group of substances or combination of substances subject to the proposed rulemaking is appropriately considered in a single proceeding;

(b) Whether the substance or group of substances subject to the rulemaking meets the definition of a potential occupational carcinogen set forth in §1990.103, including whether the scientific studies are reliable;

(c) Whether the available data can appropriately be applied to the substance, group of substances or combination of substances covered by the rulemaking;

(d) Whether information, data, and views that are submitted in accordance with §1990.144 are sufficient to warrant an exception to this part;

(e) Whether the data, views and arguments that are submitted in accordance with §1990.145 are sufficient to warrant amendment of this part;

(f) Whether the potential occupational carcinogen meets the criteria for a Category I Potential Carcinogen or a Category II Potential Carcinogen.

(g) The environmental impact arising from regulation of the substance;

(h) Any issues required by statute or executive order;

(i) The determination of the level to control exposures to Category I Potential Carcinogens primarily through the use of engineering and work practice controls including technological and economic considerations.

(j) The determination of the appropriate employee exposure level, consistent with the Act's requirements, for Category II Potential Carcinogens;

(k) Whether suitable substitutes are available for one or more uses of Category I Potential Carcinogens and; if so, the no occupational exposure level to be achieved solely with engineering and work practice controls and other issues relevant to substitution; and

(l) Whether the provisions of the proposal and of §§1990.151 and 1990.152 (model standards) are appropriate, except as limited by §1990.142 and whether additional regulatory provisions may be appropriate.

[45 FR 5282, Jan. 22, 1980, as amended at 46 FR 5881, Jan. 21, 1981]

§1990.147 Final action.

(a) Within one hundred twenty (120) days from the last day of any hearing or ninety (90) days from the close of any post hearing comment period, whichever occurs first, the Secretary shall publish in the FEDERAL REGISTER:

(1) A final standard based upon the record in the proceeding; or

(2) A statement that no final standard will be issued, and the reasons therefor, or

(3) A statement that the Secretary intends to issue a final rule, but that he is unable to do so at the present time, including:

(i) The reasons therefor; and

(ii) The date by which the standard will be published, which may not exceed one hundred twenty (120) days thereafter.

(iii) The Secretary may issue no more than one such notice, unless the Secretary determines that (A) new evidence which was unavailable during the rulemaking proceeding has just become available; (B) the evidence is so important that a final rule could not

reasonably be issued without this evidence, and; (C) the record is reopened for receipt of comments and/or a hearing on this evidence. This paragraph does not require the Secretary to consider any evidence which is submitted after the dates established for the submission of evidence.

(b) The failure of the Secretary to comply with the required timeframes shall not be a basis to set aside any standard or to require the issuance of a new proposal on any individual substance.

(c) The final standard shall state whether the substance or group of substances subject to the rulemaking is classified as a Category I Potential Carcinogen or as a Category II Potential Carcinogen. If the classification differs from that in the notice of proposed rulemaking, the Secretary shall explain the reasons for the change in classification in the preamble to the final standard.

(d) If the substance is classified as a Category I Potential Carcinogen, the final standard shall conform to the provisions of §1990.142(a)(2)(iii). If the final standard contains other provisions that substantially differ from the proposed provisions, the Secretary shall explain the reasons for the changes in the preamble to the final standard.

(e) If the substance is classified as a Category II potential carcinogen, the final standard shall conform to the provisions of §1990.142(a)(3)(iii). If the final standard contains other provisions that substantially differ from the proposed provisions, the Secretary shall explain the reasons for the changes in the preamble to the final standard.

(f) If the substance is classified as a Category II potential carcinogen, the Secretary shall notify the applicable federal and state agencies, including the Administrator of EPA, the Director of NCI, the Director of NIEHS, the Director of NIOSH, the Commissioner of FDA and the Chairperson of CPSC of such determination and request that the applicable agencies engage in, or stimulate, further research pursuant to their legislative authority, to develop new and additional scientific data.

(g) If, after a rulemaking, the Secretary determines that the substance under consideration should not be classified as a Category I potential carcinogen or a Category II potential carcinogen, the Secretary shall publish a notice of this determination in the FEDERAL REGISTER, together with the reasons therefor.

MODEL STANDARDS

§ 1990.151 Model standard pursuant to section 6(b) of the Act.

Occupational Exposure to _____

Permanent Standard (insert section number of standard)

(a) *Scope and application*—(1) *General.* This section applies to all occupational exposures to _____ or to (specify those uses or classes of uses of _____ [Chemical Abstracts Service Registry Number 0000] which are covered by the standard, including, where appropriate, the type of exposure to be regulated by the standard) except as provided in paragraph (a)(2).

(2) *Exemptions.* This section does not apply to (insert those uses or classes of uses of _____ which are exempted from compliance with the standard, including, where appropriate,

(i) Workplaces where exposure to _____ results from solid or liquid mixtures containing a specified percentage of _____ or less;

(ii) Workplaces where another Federal agency is exercising statutory authority to prescribe or enforce standards or regulations affecting occupational exposure to _____; or

(iii) Workplaces which are appropriately addressed in a separate standard).

(b) *Definitions.*

_____ means (definition of the substance, group of substances, *or combination of substances, to be regulated*).

Action level means an airborne concentration of _____ of (insert appropriate level of exposure).

NOTE: Where appropriate, consider an action level as a limitation on requirements for periodic monitoring (para. (e)(3)), medical surveillance (para. (n)), training (para. (o)), labels (para. (p)(3)), and other provisions.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Authorized person means any person specifically authorized by the employer whose duties require the person to enter regulated areas or any person entering such an area as a designated representative of employees for the purpose of exercising the opportunity to observe monitoring procedures under paragraph (r) of this section.

Director means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health, and Health Services, or designee.

Emergency means in any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which may result in a massive release of _____ which is (insert appropriate quantitative or qualitative level of release which constitutes an emergency).

OSHA Area Office means the Area Office of the Occupational Safety and Health Administration having jurisdiction over the geographic area where the affected workplace is located.

(c) *Permissible exposure limits provisions*—(1) *Inhalation*—(i) *Time weighted average limit (TWA).* Within (insert appropriate time period) of the effective date of this section, the employer shall assure that no employee is exposed to an airborne concentration of _____in excess of: (insert appropriate exposure limit or when it is determined by the Secretary that there are available suitable substitutes for uses or classes of uses that are less hazardous to humans, the proposal shall permit no occupational exposure) as an eight (8)-hour time-weighted average.

(Where the Secretary finds that suitable substitutes for _____may exist, the determination of the _____level shall include consideration of the availability, practicability, relative degree of hazard, and economic consequences of the substitutes.)

(ii) *Ceiling limit (if appropriate).* Within (insert appropriate time period) of the effective date of this section, the employer shall assure that no employee is exposed to an airborne concentration of _____in excess of: (insert exposure limit) as averaged over any: (insert appropriate time period) during the working day.

(2) *Dermal and eye exposure.* (As appropriate.) (i) Within (insert appropriate time period) of the effective date of this section, the employer shall (If eye exposure to _____does not create a risk of cancer, insert exposure level or criteria which will prevent other adverse health effects of eye exposure to _____if any. If eye exposure creates a risk of cancer, insert exposure level or criteria which represents the level of eye exposure to _____).

(ii) Within (insert appropriate time period) of the effective date of this section, the employer shall (If skin exposure to _____does not create a risk of cancer, insert exposure level or criteria which will prevent other adverse health effects of skin exposure to _____if any. If skin exposure creates a risk of cancer, insert exposure level or criteria which represents the level of skin exposure to _____).

(d) *Notification of use and emergencies*—(1) *Use.* Within (insert appropriate time period and additional information requirements if appropriate), of the effective date of this standard or within thirty days of the introduction of _____ into the workplace, every employer who has a place of employment in which _____ is present shall report the address and location of each place of employment to the OSHA Area Office and an estimate of the number of employees exposed.

(2) *Emergencies.* Emergencies, and the facts obtainable at that time, shall be reported within (insert appropriate number) hours of, or during the first federal working day after, the time the employer becomes aware of the emergency to the OSHA Area Office, whichever is longer. Upon request of the OSHA Area Office, the employer shall submit additional information in writing relevant to the nature and extent of employee exposures and measures taken to prevent future emergencies of a similar nature.

(e) *Exposure monitoring*—(1) *General.* (i) Determinations of airborne exposure levels shall be made from air samples that are representative of each employee's exposure to _____ over an eight (8) hour period. (Modify the time period as appropriate to be practical in the relevant industries yet reasonably representative of full shift exposures.) Monitoring of exposure levels required under this paragraph shall be made as

follows: [insert method or alternative methods to be used to meet the requirements of this paragraph].

(ii) For the purpose of this section, employee exposure is that exposure which would occur if the employee were not using a respirator.

(2) *Initial monitoring.* Each employer who has one or more workplaces where (specify the types of workplaces subject to the monitoring requirement) shall, within (insert appropriate period) of the effective date of this section (insert requirements for initial monitoring, as appropriate).

(3) *Frequency.* (Insert, if appropriate, provisions prescribing the minimum frequency at which monitoring must be repeated, the conditions under which such frequency must be increased or may be reduced, and conditions under which such routine monitoring may be discontinued (for example, where the action level is not exceeded). Where appropriate, specify different frequency requirements for certain types of workplaces where, for example, exposure levels are subject to greater or less variability.)

(4) *Additional monitoring.* (Insert, if appropriate, provisions for monitoring, in addition to the requirements (if any) of paragraph (e)(3). This may include a production, process, control or personnel change which might result in new or additional exposure to _____,

or whenever the employer has any other reason to suspect a change which might result in new or additional exposures to _____.)

(5) *Employee notification.* (i) Within (insert appropriate period) after the receipt of monitoring results, the employer shall notify each employee in writing of the results which represent that employee's exposure.

(ii) Whenever the results indicate that the representative employee exposure exceeds the permissible exposure limits, the employer shall include in the written notice a statement that the permissible exposure limits were exceeded and a description of the corrective action being taken to reduce exposure to or below the permissible exposure limits.

(6) *Accuracy of measurement.* (Insert requirements for accuracy of methods of measurement or detection used to comply with the paragraph).

(f) *Regulated areas*—(1) Within (insert appropriate time period) of the effective date of this section, the employer shall, where practicable, establish regulated areas where _____ concentrations are in excess of the permissible exposure limits.

(2) Regulated areas shall be demarcated and segregated from the rest of the workplace, in any manner that minimizes the number of persons who will be exposed to _____.

(3) Access to regulated areas shall be limited to authorized persons or to persons otherwise authorized by the Act or regulations issued pursuant thereto.

(4) The employer shall assure that in the regulated area, food or beverages are not present or consumed, smoking products are not present or used, and cosmetics are not applied (except that these activities may be conducted in the lunchroom, change rooms and showers required under paragraphs (m)(1) through (m)(3) of this section).

(g) *Methods of compliance*—(1) *Engineering and work practice controls.* (i) The employer shall institute engineering or work practice controls to reduce and maintain employee exposures to _____ to or below the permissible exposure limits, except to the extent that the employer establishes that such controls are not feasible.

(ii) Engineering and work practice controls shall be implemented to reduce exposures even if they will not be sufficient to reduce exposures to or below the permissible exposure limits.

(2) *Compliance program.* (i) Within (insert appropriate period) of the effective date of this section, the employer shall establish and implement a written program to reduce exposures to or below the permissible exposure limits by means of engineering and work practice controls, as required by paragraph (g)(1) of this section.

(ii) Written plans for these compliance programs shall include at least the following:

(A) A description of each operation or process resulting in employee exposure to _____;

(B) Engineering plans and other studies contemplated or used to determine the controls for each process;

(C) A report of the technology considered or to be considered in meeting the permissible exposure limits;

(D) A detailed schedule for the implementation of engineering or work practice controls; and

(E) Other relevant information reasonably requested by OSHA.

(iii) Written plans for such a program shall be submitted, upon request, to the Assistant Secretary and the Director, and shall be available at the worksite for examination and copying by the Assistant Secretary, the Director, or any affected employee or designated representative.

(iv) The plans required by this paragraph shall be revised and updated periodically to reflect the current status of the program.

(h) *Respiratory protection*—(1) *General.* The employer shall assure that respirators are used where required pursuant to this section to reduce employee exposures to or below the permissible exposure limits and in emergencies. Compliance with the permissible exposure limits may not be achieved by the use of respirators except:

(i) During the time period necessary to install or implement feasible engineering and work practice controls; or

(ii) In work operations in which the employer establishes that engineering and work practice controls are not feasible; or

(iii) In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the permissible exposure limits; or

(iv) In emergencies.

(2) *Respirator selection.* (i) Where respiratory protection is required under this section, the employer shall select and provide at no cost to the employee, the appropriate type of respirator from Table 1 below and shall assure that the employee wears the respirator provided.

TABLE 1—RESPIRATORY PROTECTION

FOR _____

(The table will contain a listing of the appropriate type of respirator for various conditions of exposure to _____).

(ii) The employer shall select respirators from those approved by the National Institute for Occupational Safety and Health under the provisions of 30 CFR part 11.

(3) *Respirator program.* (i) The employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134 (b), (d), (e), and (f).

(ii) Employees who wear respirators shall be allowed to wash their face and respirator facepiece to prevent potential skin irritation associated with respirator use.

(iii) The employer shall assure that the respirator issued to each employee is properly fitted (as appropriate, indicate the requirement for a qualitative or quantitative respirator fit testing program).

(i) *Emergency situations*—(1) *Written plans.* (i) A written plan for emergency situations shall be developed for each workplace where _____ is present. Appropriate portions of the plan shall be implemented in the event of an emergency.

(ii) The plan shall specifically provide that employees engaged in correcting emergency conditions shall be equipped with respirators as required in paragraph (h) of this section and other necessary personal protective equipment as required in paragraph (j) until the emergency is abated.

(2) *Alerting employees*—(i) *Alarms.* Where there is the possibility of employee exposure to _____ due to the occurrence of an emergency, a general alarm shall be installed and maintained to promptly alert employees of such occurrences.

(ii) *Evacuation.* Employees not engaged in correcting the emergency shall be restricted from the area and shall not be permitted to return until the emergency is abated.

(j) *Protective clothing and equipment*—(1) *Provision and use.* Where employees are exposed to eye or skin contact with _____ (insert criteria which trigger this requirement as appropriate), the employer shall, within (insert appropriate time period) of the effective date of this section provide at no cost to such employees, and assure that such employees wear, appropriate protective clothing or other equipment in accordance with 29 CFR 1910.132 and 1910.133 to protect the area of the body which may come in contact with _____.

(2) *Cleaning and replacement.* (i) The employer shall clean, launder, maintain, or replace protective clothing and equipment required to maintain their effectiveness.

(k) *Housekeeping*—(1) *General.* The employer shall, within appropriate time period of the effective date of this section, implement a housekeeping program to minimize accumulation of _____.

(2) *Specific provisions.* The program shall include (insert appropriate elements).

(i) Periodic scheduling of routine housekeeping.

(ii) Provision for periodic cleaning of dust collection systems.

(iii) Provision for maintaining clean surfaces.

(iv) Provision for assigning personnel to housekeeping procedures; and the

(v) Provision for informing employees about housekeeping program.

(l) *Waste disposal*—(1) *General.* The employer shall assure that no waste material containing _____ is dispersed into the workplace, to the extent practicable.

(2) The employer shall label, or otherwise inform employees who may contact waste material containing _____, the contents of such waste material.

(3) (Insert specific disposal methods, as appropriate.)

(m) *Hygiene facilities and practices.* Where employees are exposed to airborne concentrations of _____ in excess of the permissible exposure limits specified in paragraph (c)(1), or where employees are required to wear protective clothing or equipment pursuant to paragraph (j) of this section, or where otherwise found to be appropriate, the following facilities shall be provided by the employer for the use of those employees and the employer shall assure that the employees use the facilities provided.

[Specify appropriate hygiene facilities and practices such as]:

(1) *Change rooms.* The employer shall provide clean change rooms in accordance with 29 CFR 1910.141(e).

(2) *Showers.* (i) The employer shall provide shower facilities in accordance with 29 CFR 1910.141(d)(3).

(ii) The employer shall assure that employees exposed to _____ shower at the end of the work shift.

(3) *Lunchrooms* (if appropriate or other suitable requirements depending on the circumstances). Whenever food or beverages are consumed in the workplace, the employer shall provide lunchroom facilities which have a temperature controlled, positive pressure, filtered air supply, and which are readily accessible to employees exposed to _____.

(n) *Medical surveillance*—(1) *General.* (i) The employer shall institute a program of medical surveillance for (specify the types of employees subject to the medical surveillance requirement, for example, by specifying the level, duration, and frequency of exposure to _____ which make medical surveillance appropriate for individual employees). The employer shall provide each such employee with an opportunity for medical examinations and tests in accordance with this paragraph.

(ii) The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a licensed physician, and shall be provided without cost to the employee.

(2) *Initial examinations.* Within (insert appropriate time period) of the effective date of this section or thereafter at the time of initial assignment, the employer shall provide each employee specified in paragraph (n)(1) of this section an opportunity for a medical examination, including at least the following elements:

(i) A work history and a medical history which shall include: (insert specific areas to be covered pertinent to the health hazards posed by _____).

(ii) A physical examination which shall include: (insert specific tests, procedures, etc., pertinent to the health hazards posed by _____.) Where appropriate, provide that the examining physician shall conduct such additional examinations and tests as are needed according to his professional judgment).

NOTE: Where appropriate, require or permit different medical protocols, or different frequencies of medical examinations, for separate sub-populations of employees covered under paragraph (n)(1).

(3) *Periodic examinations.* (i) The employer shall provide the examinations specified below in this subparagraph at least (insert appropriate time) for all employees specified in paragraph (n)(3)(i) of this section: (insert appropriate medical protocol for periodic examinations).

(ii) If an employee has not had the examinations prescribed in paragraph (n)(3)(i) of this section within (insert appropriate time period) prior to termination of employment, the employer shall make such examination available to the employee upon such termination.

(4) *Additional examinations.* If the employee for any reason develops signs or symptoms commonly associated with exposure to _____, the employer shall provide appropriate examination and emergency medical treatment.

(5) *Information provided to the physician.* The employer shall provide the following information to the examining physician:

(i) A copy of this standard and its appendices;

(ii) A description of the affected employee's duties as they relate to the employee's exposure;

(iii) The employee's actual or representative exposure level;

(iv) The employee's anticipated or estimated exposure level (for preplacement examinations or in cases of exposure due to an emergency);

(v) A description of any personal protective equipment used or to be used; and

(vi) The names and addresses of physicians who, under the sponsorship of the employer, provided previous medical examinations of the affected employee, if such records are not otherwise available to the examining physician.

(6) *Physician's written opinion.* (i) The employer shall obtain a written opinion from the examining physician which shall include:

(A) The physician's certification that he has received the information from the employer required under the paragraph (n)(5) and has performed all medical examinations and tests which are in his opinion appropriate under this standard;

(B) The physician's opinion as to whether the employee has any detected medical condition which would place the employee at an increased risk of material impairment of the employee's health from exposure to _____;

(C) Any recommended limitations upon the employee's exposure to _____ or upon the use of protective clothing and equipment such as respirators; and

(D) A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions which require further examination or treatment.

(ii) The employer shall instruct the physician not to reveal in the written opinion specific findings or diagnoses unrelated to occupational exposure to _____;

(iii) The employer shall provide a copy of the written opinion to the affected employee.

(o) *Employee information and training*—(1) *Training program.* (i) Within (insert appropriate time period) from the effective date of this section, the employer shall institute a training program for all employees who (specify the employees subject to the training requirement), and shall assure their participation in the training program.

(ii) The training program shall be provided at the time of initial assignment, or upon institution of the training program, and at least (insert appropriate time period) thereafter, and the employer shall assure that each employee is informed of the following:

NOTE: Specify, as appropriate, some or all of the following information, or any other appropriate information. Where appropriate, require training programs with different contents, or different frequencies, for separate subpopulations of the employees specified in paragraph (o)(1).

(A) The information contained in the Appendices;

(B) The quantity, location, manner of use, release or storage of _____ and the specific nature of operations which could result in exposure to _____, as well as any necessary protective steps;

(C) The purpose, proper use, and limitations of respirators;

(D) The purpose and a description of the medical surveillance program required by paragraph (n) of this section;

(E) The emergency procedures developed, as required by paragraph (i) of this section;

(F) The engineering and work practice controls, their function and the employee's relationship thereto; and

(G) A review of this standard.

(2) *Access to training materials.* (i) The employer shall make a copy of this standard and its appendices readily available to all affected employees.

(ii) The employer shall provide, upon request, all materials relating to the employee information and training program to the Assistant Secretary and the Director.

(p) *Signs and labels*—(1) *General.* (i) The employer may use labels or signs required by other statutes, regulations, or ordinances in addition to, or in combination with, signs and labels required by this paragraph.

(ii) The employer shall assure that no statement appears on or near any sign or label, required by this paragraph, which contradicts or detracts from the meaning of the required sign or label.

(2) *Signs.* (i) The employer shall post signs to clearly indicate all workplaces. (Specify as appropriate the description of the area to be signposted such as ''where employees are exposed to _____,'' or ''where exposures exceed the action level,'' or ''where exposures exceed the PEL,'' or ''which are regulated areas''). The signs shall bear the following legend:

DANGER

_____

(insert appropriate trade or common names)

CANCER HAZARD

AUTHORIZED PERSONNEL ONLY

(ii) The employer shall assure that signs required by this paragraph are illuminated and cleaned as necessary so that the legend is readily visible.

(iii) Where airborne concentrations of _____ exceed the permissible exposure limits, the signs shall bear the additional legend: ''Respirator Required'' or ''Respirator May Be Required'' as appropriate.

(3) *Labels.* (i) The employer shall assure that precautionary labels are affixed to all containers of _____ and of products containing _____ (specify if appropriate suitable modifications), and that the labels remain affixed when the _____ or products containing _____ are sold, distributed or otherwise leave the employer's workplace.

(ii) The employer shall assure that the precautionary labels required by this paragraph are readily visible and legible. The labels shall bear the following legend:

DANGER

CONTAINS _____

CANCER HAZARD

NOTE: Utilize the clause ''POTENTIAL CANCER HAZARD'' if it is appropriate to include a signs and labels provision for a Category II potential carcinogen.

(q) *Recordkeeping*—(1) *Exposure monitoring.* (i) The employer shall establish and maintain an accurate record of all monitoring required by paragraph (e) of this section.

(ii) This record shall include:

(A) The dates, number, duration, and results of each of the samples taken, including a description of the sampling procedure used to determine representative employees exposure;

(B) A description of the sampling and analytical methods used;

(C) Type of respiratory protective devices worn, if any; and

(D) Name, social security number and job classification of the employees monitored and of all other employees whose exposure the measurement is intended to represent.

(iii) The employer shall maintain this record for (insert appropriate period) or for the duration of employment plus (insert appropriate period) whichever is longer.

(2) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record of each employee subject to medical surveillance as required by paragraph (n) of this section.

(ii) This record shall include:

(A) A copy of the physicians' written opinions or a written explanation of

the absence of any such opinion or employee refusal to take the medical examination:

(B) Any employees medical complaints related to exposure to _____;

(C) A copy of the information provided to the physician as required by paragraphs (n)(5)(ii) through (v) of this section unless it is systematically retained elsewhere by the employer for the period of time specified in paragraph (q)(2)(ii); and

(D) A copy of the employee's work history.

(iii) The employer shall assure that this record be maintained for (insert appropriate period) or for the duration of employment plus (insert appropriate period) whichever is longer.

(3) *Availability.* (i) The employer shall assure that all records required to be maintained by this section be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) Employee exposure measurement records and employee medical records required by this section shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20(a) through (e) and (g) through (i).

(4) *Transfer of records.* (i) Whenever the employer ceases to do business, the successor employer shall receive and retain all records required to be maintained by this section.

(ii) Whenever the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, these records shall be transmitted to the Director.

(iii) At the expiration of the retention period for the records required to be maintained pursuant to this section, the employer shall transmit these records to the Director.

(iv) The employer shall also comply with any additional requirements involving transfer of records set forth in 29 CFR 1910.20(h).

NOTE: Include other recordkeeping requirements if appropriate.

(r) *Observation of monitoring*—(1) *Employee observation.* The employer shall provide affected employees, or their designated representatives, an opportunity to observe any monitoring of employee exposure to _____ conducted pursuant to paragraph (e) of this section.

(2) *Observation procedures.* (i) Whenever observation of the monitoring of employee exposure to _____ requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with personal protective clothing or equipment required to be worn by employees working in the area, assure the use of such clothing and equipment, and require the observer to comply with all other applicable safety and health procedures.

(ii) Without interfering with the monitoring, observers shall be entitled to:

(A) Receive an explanation of the measurement procedures;

(B) Observe all steps related to the measurement of airborne concentrations of _____ performed at the place of exposure; and

(C) Record the results obtained, and receive results supplied by the laboratory.

(s) *Effective date.* This section shall become effective (insert effective date).

(t) *Appendices.* The information contained in the appendices is not intended, by itself, to create any additional obligations not otherwise imposed or to detract from any existing obligation. (In normal circumstances three appendices will be included in each standard, an ''Appendix A—Substance Safety Data Sheet,'' an ''Appendix B—Substance Technical Guidelines,'' and an ''Appendix C—Medical Surveillance Guidelines.'' Insert additional appendices or delete any of the suggested appendices as appropriate.)

[45 FR 5282, Jan. 22, 1980; 45 FR 43405–43406, June 27, 1980, as amended at 46 FR 5881, Jan. 21, 1981]

§ 1990.152 Model emergency temporary standard pursuant to section 6(c) of the Act.

Occupational Exposure to _____;

Emergency Temporary Standard (insert section number of standard)

(a) *Scope and application*—(1) *General.* This section applies to all occupational exposures to _____, or to (specify the uses of classes of uses of _____ [Chemical Abstracts Service Registry Number 00000], which are covered by the standard, including, where appropriate, the type of exposure to be regulated by the standard) except as provided in paragraph (a)(2).

(2) *Exemption.* This section does not apply to (insert those uses or classes of uses of _____ which are exempted from compliance with the standard, including, where appropriate,

(i) Workplaces where exposure to _____ results from solid or liquid mixtures containing a specified percentage of _____ or less;

(ii) Workplaces where another Federal agency is exercising statutory authority to prescribe or enforce standards or regulations affecting occupational exposure to _____ or

(iii) Workplaces which are appropriately addressed in a separate standard.

(b) *Definitions.*

_____ means (definition of the substance, group of substances, or combination of substances, to be regulated).

Action level means an airborne concentration of _____ of (insert appropriate level of exposure).

NOTE: Where appropriate, consider an action level as a limitation on requirements for periodic monitoring (para. (e)(3)), medical surveillance (para. (n)), training (para, (o)), and other provisions.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Authorized person means any person specifically authorized by the employer whose duties require the person to enter a regulated area or any person entering such an area as a designated representative of employees exercising the opportunity to observe monitoring procedures under paragraph (r) of this section.

Director means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health, Education and Welfare, or designee.

Emergency means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which may result in a release of _____ which is (insert appropriate quantitative or qualitative level of release which constitutes an emergency).

OSHA Area Office means the Area Office of the Occupational Safety and Health Administration having jurisdiction over the geographic area where the affected workplace is located.

(c) *Permissible exposure limits*—(1) *Inhalation*—(i) *Time-weighted average limit (TWA).* Within (insert appropriate time) from the effective date of this emergency temporary standard, the employer shall assure that no employee is exposed to an airborne concentration of _____in excess of: (insert appropriate exposure limit representing a level that can be complied with immediately) as an eight (8)-hour time-weighted average.

(ii) *Ceiling limit (if appropriate).* The employer shall assure that no employee is exposed to an airborne concentration of _____in excess of: (insert appropriate exposure limit representing a level that can be complied with immediately) as averaged over any: (insert appropriate time period) during the working day.

(2) *Dermal and eye exposure.* (As appropriate.) (i) Within (insert appropriate time period) of the effective date of this section, the employer shall (If eye exposure to _____does not create a risk of cancer, insert exposure level or criteria which will prevent other adverse effects of eye exposure to _____, if any. If eye exposure creates a risk of cancer, insert exposure level or criteria which represent the level of eye exposure to _____.)

(ii) Within (insert appropriate time period) of the effective date of this section, the employer shall (If skin exposure to _____does not create a risk of cancer, insert exposure level or criteria which will prevent other adverse health affects of skin exposure to

_____if any. If skin exposure creates a risk of cancer, insert exposure level or criteria which represents the level of skin exposure to _____).

(d) *Notification of use.* Within (insert appropriate time and omit specific categories of information if appropriate) of the effective date of this section, or within fifteen (15) days following the introduction of _____ into the workplace, every employer shall report the following information to the nearest OSHA Area Office for each such workplace:

(1) The address and location of each workplace in which _____ is present;

(2) A brief description of each process or operation which may result in employee exposure to _____;

(3) The number of employees engaged in each process or operation who may be exposed _____ and an estimate of the frequency and degree of exposure that occurs; and

(4) A brief description of the employer's safety and health program as it relates to limitation of employee exposure to _____;

(e) *Exposure monitoring*—(1) *General.* (i) Determinations of airborne exposure levels shall be made from air samples that are representative of each employee's exposure to _____ over an eight (8) hour period. (Modify the time period as appropriate to be practical in the relevant industries yet reasonably representative of full shift exposures). Monitoring of exposure levels required under this paragraph shall be made as follows: [insert method or alternative methods to be used to meet the requirements of this paragraph].

(ii) For the purposes of this section, employee exposure is that exposure which would occur if the employee were not using a respirator.

(2) *Initial monitoring.* Each employer who has one or more workplaces where (specify the types of workplaces subject to the monitoring requirement), shall within (insert appropriate period) of the effective date of this section (insert requirements for initial monitoring, as appropriate).

(3) *Frequency.* (Insert, if appropriate, provisions prescribing the minimum frequency at which monitoring must be repeated, the conditions under which such frequency must be increased, or may be reduced, and conditions under which such routine monitoring may be discontinued (for example where the action level is not exceeded). Where appropriate, specify different frequency requirements for certain types of workplaces where, for example, exposure levels are subject to greater or less variability.)

(4) *Additional monitoring.* (Insert, if appropriate, provisions for monitoring, in addition to the requirements (if any) of paragraph (e)(3). This may include a production, process, control or personnel change which might result in new or additional exposure to _____ or whenever the employer has any other reason to suspect a change which might result in new or additional exposures to _____.)

(5) *Employee notification.* (i) Within (insert appropriate period) after the receipt of monitoring results, the employer shall notify each employee in writing of the results which represent that employee's exposure.

(ii) Whenever the results indicate that the representative employee exposure exceeds the permissible exposure limits, the employer shall include in the written notice a statement that permissible exposure limits were exceeded and a description of the corrective action being taken to reduce exposure to or below the permissible exposure limits.

(6) *Accuracy of measurement.* (Insert requirements for accuracy of methods of measurement or detection used to comply with the paragraph.)

(f) [Reserved]

(g) *Methods of compliance*—(1) *General.* (i) Employee exposures to _____ shall be controlled to or below the permissible exposure limits by any practicable combination of engineering controls, work practices and personal protective devices and equipment, during the effective period of this emergency temporary standard.

NOTE: Where engineering controls or work practices can reduce employee exposures to _____ it is recommended that they be implemented where practicable, even where they do not themselves reduce exposures to, or below the permissible exposure limits. Work practices which can be implemented by the employer to help reduce employee exposures to _____ include limiting access to work areas to authorized personnel, prohibiting

smoking and consumption of food and beverages in work areas, and establishing good maintance and housekeeping practices, including the prompt clean-up of spills and repair of leaks.

(2) *Engineering and work practice control plan.* (i) Within (insert appropriate time period) of the effective date of this emergency temporary standard, the employer shall develop a written plan describing proposed means to reduce employee exposures to the lowest feasible level by means of engineering and work practice controls (which will be eventually required by a permanent standard for occupational exposure to _____, as provided for by §1990.151(g) of this subpart).

(ii) Written plans required by this paragraph shall be submitted, upon request, to the Assistant Secretary and the Director and shall be available at the worksite for examination and copying by the Assistant Secretary, the Director, and any affected employee or designated representative.

(h) *Respiratory protection*—(1) *Required use.* The employer shall assure that respirators are used where required pursuant to this section to reduce employee exposures to within the permissible exposure limits and in emergencies.

(2) *Respirator selection.* (i) Where respiratory protection is required under this section, the employer shall select and provide at no cost to the employee, the appropriate respirator from Table 1 below and shall assure that the employee wears the respirator provided.

TABLE 1—RESPIRATORY PROTECTION FOR _____

(The table will contain a listing of the appropriate type of respirator for various conditions of exposure to _____.)

(ii) The employer shall select respirators from those approved by the National Institute for Occupational Safety and Health under the provisions of 30 CFR part 11.

(3) *Respirator program.* (i) The employer shall institute a respirator protection program in accordance with 29 CFR 1910.134 (b), (d), (e) and (f).

(ii) Employees who wear respirators shall be allowed to wash their face and respirator face piece to prevent potential skin irritation associated with respirator use.

(iii) The employer shall assure that the respirator issued to each employee is properly fitted (as appropriate, indicate the requirement for a qualitative or quantitative respirator fit testing program.)

(i) [Reserved]

(j) *Protective clothing and equipment*—(1) *Provision and use.* Where employees are exposed to eye or skin contact with _____ (insert criteria which trigger this requirement as appropriate), the employer shall within (insert appropriate time period) of the effective date of this standard provide, at no cost to the employees, and assure that employees wear, appropriate protective clothing or other equipment in accordance with 29 CFR 1910.132 and 1910.133 to protect the area of the body which may come in contact with _____.

(2) *Cleaning and replacement.* (i) The employer shall clean, launder, maintain, or replace protective clothing and equipment required by this paragraph, as needed to maintain their effectiveness.

(k) *Housekeeping*—(1) *General.* The employer shall, within (insert appropriate time period) of the effective date of this section, implement a housekeeping program to minimize accumulations of _____.

(2) *Specific provisions.* The program shall include (insert appropriate elements):

(i) Periodic scheduling of routine housekeeping procedures;

(ii) Provision for periodic cleaning of dust collection systems;

(iii) Provision for maintaining clean surfaces;

(iv) Provision for assigning personnel to housekeeping procedures; and

(v) Provision for informing employees about housekeeping program.

(l) *Waste disposal*—(1) *General.* The employer shall assure that no waste material containing _____ is dispersed into the workplace, to the extent practicable.

(2) The employer shall label, or otherwise inform employees who may contact waste material containing _____ of the contents of such waste material.

(3) (Insert specific disposal methods, as appropriate.)

(m) [Reserved]

(n) *Medical surveillance*—(1) *General.* (i) The employer shall institute a program of medical surveillance for (specify the types of employees subject to the medical surveillance requirement, for example, by specifying the level, duration, and frequency of exposure to _____ which make medical surveillance appropriate for individual employees). The employer shall provide each such employee with an opportunity for medical examinations and tests in accordance with this paragraph.

(ii) The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a licensed physician, and shall be provided without cost to the employee.

(2) *Initial examinations.* Within (insert appropriate time period) of the effective date of this section, or thereafter at the time of initial assignment, the employer shall provide each employee specified in paragraph (n)(1) of this section an opportunity for a medical examination, including at least the following elements:

(i) A work history and a medical history which shall include (insert specific areas to be covered pertinent to the health hazards posed by _____).

(ii) A physical examination which shall include: (insert specific tests, procedures, etc., pertinent to the health hazards posed by _____. Where appropriate, provide that the examining physician shall conduct such additional examinations and tests as are needed according to his professional judgement).

NOTE: Where appropriate, require or permit different medical protocols, or different frequencies of medical examinations, for separate sub-populations of employees covered under paragaph (n)(1).

(3) *Periodic examinations.* (If appropriate insert appropriate medical protocol and time.)

(4) *Additional examinations.* If the employee for any reason develops signs or symptoms commonly associated with exposure to _____, the employer shall provide an appropriate examination and emergency medical treatment.

(5) *Information provided to the physician.* The employer shall provide the following information to the examining physician:

(i) A copy of this emergency temporary standard and its appendices;

(ii) A description of the affected employee's duties as they relate to the employee's exposure;

(iii) The employee's actual or representative exposure level;

(iv) The employee's anticipated or estimated exposure level (for preplacement examinations or in cases of exposures due to an emergency);

(v) A description of any personal protective equipment used or to be used; and

(vi) The names and addresses of physicians who, under the sponsorship of the employer, provided previous medical examinations of the affected employee, if such records are not otherwise available to the examining physician.

(6) *Physician's written opinion.* (i) The employer shall obtain a written opinion from the examining physician which shall include:

(A) The results of the medical tests performed;

(B) The physician's opinion as to whether the employee has any detected medical condition which would place the employee at an increased risk of material impairment of the employee's health from exposure to _____;

(C) Any recommended limitations upon the employee's exposure to _____ or upon the use of protective clothing and equipment such as respirators; and

(D) A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions which require further examination or treatment.

(ii) The employer shall instruct the physician not to reveal in the written opinion specific findings or diagnoses unrelated to occupational exposure to _____;

(iii) The employer shall provide a copy of the written opinion to the affected employee.

(o) *Employee information and training*—(1) *Training program.* (i) Within (insert appropriate time period) from the effective date of this standard, the employer shall institute a training program for all employees who (specify

the employees subject to the training requirement), and shall assure their participation in the training program.

(ii) The employer shall assure that each employee is informed of the following:

(A) The information contained in the Appendices;

(B) The quantity, location, manner of use, release, or storage of _____ and the specific nature of operations which could result in exposure to _____, as well as any necessary protective steps;

(C) The purpose, proper use, and limitations of respirators;

(D) The purpose and description of the medical surveillance program required by paragraph (n) of this section; and

(E) A review of this standard.

(2) *Access to training materials.* (i) The employer shall make a copy of this standard and its appendices readily available to all affected employees.

(ii) The employer shall provide, upon request, all materials relating to the employee information and training program to the Assistant Secretary and the Director.

(p) *Signs and labels* (include a signs or a signs and labels provision if it is appropriate for the duration of the ETS)—(1) *General.* (i) The employer may use labels or signs required by other statutes, regulations, or ordinances in addition to, or in combination with, signs and labels required by this paragraph.

(ii) The employer shall assure that no statement appears on or near any sign or label, required by this paragraph, which contradicts or detracts from the meaning of the required sign or label.

(2) *Signs.* (i) The employer shall post signs to clearly indicate all workplaces (specify as appropriate the description of the area to be signposted such as ''where employees are exposed to _____,'' or ''where exposures exceed the PEL,'' or ''which are regulated areas''). The signs shall bear the following legend:

DANGER

_____

(insert appropriate trade or common names)

CANCER HAZARD

AUTHORIZED PERSONNEL ONLY

(ii) The employer shall assure that signs required by this paragraph are illuminated and cleaned as necessary so that the legend is readily visible.

(iii) Where airborne concentrations of _____ exceed the permissible exposure limits, the signs shall bear the additional legend: (''Respirator Required'' or ''Respirator may be Required'' as appropriate).

(3) *Labels.* (i) The employer shall assure that precautionary labels are affixed to all containers of _____ and of products containing _____ (specify if appropriate suitable modifications), and that the labels remain affixed when _____ or products containing _____ are sold, distributed or otherwise leave the employer's workplace.

(ii) The employer shall assure that the precautionary labels required by this paragraph are readily visible and legible. The labels shall bear the following legend:

DANGER

CONTAINS _____

CANCER HAZARD

(q) *Recordkeeping*—(1) *Exposure monitoring.* (i) The employer shall establish and maintain an accurate record of all monitoring required by paragraph (e) of this section.

(ii) This record shall include:

(A) The dates, number, duration, and results of each of the samples taken, including a description of the sampling procedures used to determine representative employee exposure;

(B) A description of the sampling and analytical methods used;

(C) Type of respiratory protective devices worn, if any; and

(D) Name, social security number, and job classification of the employee monitored and of all other employees whose exposure the measurement is intended to represent.

(iii) The employer shall maintain this record for the effective period of this emergency temporary standard, and for any additional period required by the permanent standard.

(2) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance as required by paragraph (n) of this section.

(ii) This record shall include:

(A) A copy of the physicians' written opinions or a written explanation of the absence of any such opinion or employee refusal to take the medical examination;

(B) Any employee medical complaints related to exposure to _____;

(C) A copy of the information provided to the physician as required by paragraphs (n)(5)(ii)–(iv) of this section unless it is systematically retained elsewhere by the employer for the period of time specified in paragraph (q)(2)(iii); and,

(D) A copy of the employee's work history. (*1*) The employer shall assure that employee exposure measurement records, as required by this section, be made available upon request to the Assistant Secretary and the Director for examination and copying.

(iii) The employer shall assure that this record be maintained for the effective period of this emergency temporary standard, and for any additional period required by the permanent standard.

(3) *Availability.* (i) The employer shall assure that all records required to be maintained by this section be made available upon request, to the Assistant Secretary and the Director for examination and copying.

(ii) Employee exposure measurement records and employee medical records required by this section shall be provided upon request to employees, designated representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20 (a) through (e) and (g) through (i).

(r) *Observation of monitoring.* (1) Employee observation. The employer shall provide affected employees, or their designated representatives, an opportunity to observe any monitoring of employee exposure to _____ conducted pursuant to paragraph (e) of this section.

(2) *Observation procedures.* (i) Whenever observation of the monitoring of employee exposure to _____ requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with personal protective clothing or equipment required to be worn by employees working in the area, assure the use of such clothing and equipment, and require the observer to comply with all other applicable safety and health procedures.

(ii) Without interfering with the monitoring, observers shall be entitled to:

(A) Receive an explanation of measurement procedures;

(B) Observe all steps related to the measurement of airborne concentrations of _____ performed at the place of exposure; and

(C) Record the results obtained and receive results supplied by the laboratory.

(s) *Effective date.* This section shall become effective (insert effective date).

(t) *Appendices.* The information contained in the appendices is not intended, itself, to create any additional obligations not otherwise imposed or to detract from any existing obligation. (In normal circumstances three appendices will be included in each standard, an ''Appendix A—Substance Safety Data Sheet,'' an ''Appendix B—Substance Technical Guidelines,'' and an ''Appendix C—Medical Surveillance Guidelines.'' Insert additional appendices or delete any of the suggested appendices as appropriate.)

[45 FR 5282, Jan. 22, 1980; 45 FR 43406–43407, June 27, 1980, as amended at 46 FR 5882, Jan. 21, 1981]

PARTS 1991–1999 [RESERVED]